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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,691	02/09/2001	Oliver Danne	81640	7836
75	90 03/21/2003			
KREIGSMAN & KREIGSMAN		•	EXAMINER	
665 FRANKLIN STREET FRAMINGHAM, MA 01702			COLE, MONIQUE T	
		•	ART UNIT	PAPER NUMBER
			1743	7
			DATE MAILED: 03/21/2003	/

Please find below and/or attached an Office communication concerning this application or proceeding.

Application N. Applicant(s) DANNE ET AL								
## Examiner Nonique T. Cole 1743 ## THE MAILING DATE of this c mmunication appears on the cover sheet with the corresp indence address = Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ③ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. ## THE M	•	Application N .						
Monique T. Cole	Office Action Summers	09/762,691	DANNE ET AL.					
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THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provision of 37 CR1 13(dq). In no event, however, may a reply be timey filed after \$3k (8) MCNITHS from the maining date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ARANDONED (38 U.S. C. § 13). - Pailure to reply under the maining date of this communication. - Pailure to reply within the set or extended period for reply will, by statute, cause the application to become ARANDONED (38 U.S. C. § 13). - Any reply received by the POtica set than these monits after the mailing date of this communication, even if timely filed, may reduce any - Statuse - This action is FINAL. - 2b) This action is non-final. - Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quay/e, 1935 C.D. 11, 453 O.G. 213. - Disposition of Claims - 4) Claim(s) - 1-11 is/are pending in the application. - 4a) Of the above claim(s) is/are withdrawn from consideration. - 5) Claim(s) is/are allowed. - 6) Claim(s) is/are allowed. - 7) Claim(s) is/are allowed. - 8) Claim(s) is/are allowed. - 9) The drawing(s) filed on is/are: all accepted or bl objected to by the Examiner. - 9) The drawing(s) filed on is/are: all accepted or bl								
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DETAILED ACTION

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 2. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recognizing and diagnosing acute myocardial infarction, does not reasonably provide enablement for all acute coronary syndromes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.
- 3. Upon inspection of the instant specification, it appears that all correlations are directed towards CCTD and myocardial infarction. While Applicant does point out that levels of CCTD below the limit may be indicative of other coronary troubles, such a correlation does not appear to be absolute, as is the case with myocardial infarctions. In fact, it appears that more of a correlation is made between such coronary troubles as angina pectoris and troponin levels. At best, on page 22, the specification does seem to support instable angina pectoris along with myocardial infarction which may be diagnosed based on choline measurements. The instant claims, however, are directed to CCTD measurement and content and do not consider troponin levels. Thus, the instant claims do not seem to be commensurate in scope with instant disclosure. Further clarification and/or correction is required.
- 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: there is no correlation step set forth between the diagnosis of acute myocardial infarction and the content of choline, choline and/or trimethyl ammonium derivatives. A correlation step is necessary in the instant claims because without it one of ordinary skill would be unable to ascertain how the measurement of choline would have any relation to myocardial infarction. It is suggested the instant claims be amended to reflect that an increased level in CCTD is the cause of the myocardial infarction diagnosis. See page 4 & page 18 of the specification.

Allowable Subject Matter

- 6. Claims 1-11 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, first & second paragraph, set forth in this Office action.
- 7. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest using phosphoryl choline, plasmalogen or lysoplasmenyl choline or their derivatives as a marker for the diagnosis of myocardial infarction. The closest prior art does teach the relationship between lysophophatidyl choline and myocardial infarction, but does not conclusively teach the same relationship using lysoplasmenyl choline as the diagnostic marker.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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USP 5,747,274 teaches choline kinase among other diagnostic markers as being useful

in the assessment of chest pain.

"Calcim-independent phospholipase A_2 mediates CREB phosphorylation and c-fos expression

during ischemia" teaches that lysoplasmenylcholine plays a part in the cellular pathway that

regulates myocardial ischemia.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Monique T. Cole whose telephone number is 703-305-0447.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-872-9310 for regular

communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is 703-306-0661.

Monique T. Cole

Examiner

Art Unit 1743

MC MC March 17, 2003

7 Jill Warden
Supervisory Patent Examiner

Technology Center 1700